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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 7,351,533 was filed on December 14, 2009, under 35 U.S.C. § 156. Although the application for patent term extension was received by the USPTO on December 18, 2009, Applicant properly relied upon the Certificate of Mailing provisions of 37 C.F.R. 1.8 in depositing their application for patent term extension on December 14, 2009.

The assistance of your Office is requested in confirming that the product identified in the application, CERVARIX® [Human Papillomavirus Bivalent(Types 16 & 18) Vaccine, Recombinant], has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on December 14, 2009 using the certificate of mailing provisions, was timely, given the BLA license date of October 16, 2009. Applicant, however, misidentified at section 5 on page 3 of the application the last day the application may be submitted as December 15, 2009, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus December 14, 2009, or sixty days from October 16, 2009, starting the count of the sixty-day period on October 16, 2009. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that “section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date.”

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Raymond J. Lillie
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